510(k) SUMMARY

JUN 2 5 2013

I. GENERAL INFORMATION

A. Submission Applicant and Correspondent:

Name:	EPI Mobile Health Solutions (S) Pte Ltd
Address:	302 Orchard Road, # 18-01 Tong Building, Singapore 238862
U.S. Contact:	Karl M. Nobert, Esq. Squire Sanders LLP 1200 19th Street, NW, Suite 300 Washington, DC 20032 Telephone: 202-626-6630 Fax: 202-626-6780 Email: karl.nobert@squiresanders.com

B. Name of Device:

Trade Name:	EPI Mini ECG Portable Health Monitoring System ("EPI Mini")
Common Name:	ECG Event Recorder (Cardiac Rhythm Monitor)

C. Regulatory Information:

Classification:	Cardiovascular Monitoring Device (21 CFR § 870.2340) Transmitters and Receivers Electrocardiograph, Telephone (21 CFR § 870.2920)
Product Codes:	DPS, DXH, DSH
Class:	Class II

D. Predicate Devices:

Device Trade Name	510(k) No.	Classification Name	Product Code
REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor)	K111438	Cardiovascular Monitoring Device	DPS
Signalife Fidelity 200 Cardiac Event Recorder	K071228	Transmitter and Receivers Electrocardiograph, Telephone	DXH, DSH

II. DEVICE DESCRIPTION:

The EPI Mini ECG Portable Health Monitoring System ("EPI Mini") is a portable recording device which is designed to be used in combination with an individual's smartphone to create a portable health monitoring system. Not only does the EPI Mini record and store a user's physiological data but when paired with smartphone technology is capable of wirelessly transmitting such data to a remote server for review, monitoring and interpretation by a learned intermediary, and subsequent forwarding to the user's physician when necessary.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is a portable single-channel device composed of 3 metallic electrode sensors strategically located on 3 sides of the device. The EPI Mini measures electrical differences between two points when in direct contact with the user's skin surface and is capable of recording new Electrocardiograms or ECGs every 30 seconds.

Holding the sides of the device (the metallic sensors) with their left and right hands, the user presses the "Enter" button to begin ECG recording. It takes approximately 30-45 seconds to measure an ECG.

A recorded ECG can then be sent to the user's smartphone (i.e., a mobile or cellular telephone) using patented bluetooth technology that relies on a proprietary EPI mHealth Application or "EPI mHealth App" which can be downloaded from the user's respective App store. The App allows a user to wirelessly transmit the ECG data to a remote server for monitoring by a learned intermediary, processing, storage and when necessary, forwarding on to the user's physician for

review and evaluation. From the remote server and monitoring center, the data can be delivered to a physician by mobile phone, fax, email or internet. The mHealth App also allows storage of ECGs on the user's smart phone.

The mHealth App also allows for the personal storage of a user's own physiological data such as blood pressure, blood glucose levels and cholesterol. Such stored data can be updated and retrieved for later use and also displayed in a line graph format for trend analysis. Additionally, the mHealth App permits a user to view, resend and/or delete saved data as needed.

The EPI Mini is composed of several individual components including (1) the EPI Mini portable ECG recorder, (2) a USB data cable, (3) the mHealth application which can be purchased and downloaded from the user's respective application store, and (4) a 500mAh battery.

III. INDICATIONS FOR USE

The EPI Mini Portable ECG Recorder ("EPI Mini") is intended for use with a patient's smartphone to record, store and wirelessly transmit physiological data to a remote server. It is indicated for individuals who are at risk for cardiac disease, experience transient symptoms suggesting possible cardiac arrhythmia or have existing heart conditions.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is intended for use by adults who suffer from cardio-vascular disease, are considered high risk for possible cardiovascular events or are concerned about their heart function and rhythm.

IV. SUMMARY OF TECHNICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES

The EPI Mini is substantially equivalent to the FDA-cleared REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) (K111438) ("REKA E100") and the Signalife Fidelity 200 Cardiac Event Recorder (K071228) ("Signalife").

All three of the devices are intended to record, store, transmit and receive physiological data via the user's own smartphone. They allow a user to display, send and delete his or her own personal recorded physiological data. The device is designed to measure and record personal health data, including but not limited to, a user's own ECGs.

The EPI Mini and the cited predicate devices are all intended for use by individuals at risk for cardiac disease and those who experience transient symptoms suggesting possible cardiac arrhythmia. They are also indicated for individuals who require monitoring for the detection of non-lethal cardiac arrhythmias.

Similar to the REKA E100, the EPI Mini is a 1 lead ECG event recorder that is capable of recording an ECG every 30 seconds. Both devices are capable of transferring data to a computer or mobile phone. The EPI Mini, like the REKA E100, also comes with its own mobile application software allowing the device to communicate with a user's smartphone. Finally, neither device is designed to diagnose, or signal or trigger an alarm.

As for the identified Signalife predicate device, the EPI Mini is similar in that it is also a battery operated ECG event recorder that can record an ECG in less than one minute. Following recording, both devices allow for ECGs to be transtelephonically transmitted to a cardiac monitoring station for analysis and diagnosis by a learned intermediary. Both devices are capable of storing a user's recorded ECGs for later review.

The minor design differences amongst the three devices do not affect the substantial equivalence of the devices to one another. A Substantial Equivalence Comparison Table is attached for a side-by-side comparison of the EPI Mini and the three cited predicated devices.

V. SUMMARY OF PERFORMANCE TESTING

The EPI Mini has undergone extensive verification and validation testing to confirm that it operates as intended and is safe for use. Testing has included various performance tests and software validation tests to ensure that the device satisfies all applicable functional and performance requirements. Among others, the performed testing included:

- Bench Testing to assess data integrity during the transmission of ECG data from the EPI Mini to representative smartphone technology.
- Hazard Analysis Testing in accordance with the methods suggested in EN ISO 13485 (as an alternative to EN ISO 14971).

Among others, the EPI Mini was also tested against the following performance standards:

- IEC 60601-1
- IEC 60601-2-25
- IEC 62133
- EC 13s

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

EPI Mobile Health Solutions (S) Pte Ltd
c/o Mr. Karl M. Nobert
Squire Sanders (US) LLP
1200 19th Street, NW, Suite 300
Washington, DC 20032

Re: K121628
EPI Mini ECG Portable Health Monitoring System
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH, DPS, DSH
Dated: June 3, 2013
Received: June 5, 2013

Dear Mr. Nobert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section V

Statement of Indications for Use

510(k) Number (if known): **K121628**

Device Name: EPI Mini ECG Portable Health Monitoring System ("EPI Mini")

Indications for Use:

The EPI Mini Portable ECG Recorder ("EPI Mini") is intended for use with a patient's smartphone to record, store and wirelessly transmit physiological data to a remote server. It is indicated for individuals who are at risk for cardiac disease, experience transient symptoms suggesting possible cardiac arrhythmia or have existing heart conditions.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is intended for use by adults who suffer from cardio-vascular disease, are considered high risk for possible cardiovascular events or are concerned about their heart function and rhythm.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Bram D. Zuckerman -S
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